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Cleveland, OH 44115				
EXAMINER				
CHONG, YONG SOO				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/031,851

Applicant(s)

RAPP ET AL.

Examiner

Yong S. Chong

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1.3.6-21 and 34-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1.3.6-21 and 34-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 5/8/09. Claim(s) 2, 4-5, 22-33 have been cancelled. Claim(s) 46-47 have been added. Claim(s) 1, 3, 6-21, 34-47 are pending. Claim(s) 1, 14, 34 have been amended. Claim(s) 1, 3, 6-21, 34-47 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified or repeated below for Applicant's convenience. Applicant's amendments have necessitated the following new rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim(s) 46-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "pharmaceutical preparation to the area to be treated including alkali and/or alkaline earth salts of tosylchloramide" renders the claim indefinite as to whether the tosylchloramide is actually part of the pharmaceutical preparation or not. Applicant is encouraged to use the conventional transition phrase "comprising" rather than "including" in order to show that the tosylchloramide is part of the pharmaceutical preparation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 6-21, 34-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandeveld et al. (WO 91/07876) in view of Berger (US Patent 4,574,084).

Vandeveld et al. discloses that tosylchloramide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-8 and claims 1-28). Vandeveld et al. discloses the pharmaceutical compositions of tosylchloramide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts

of Chloramin T (see Example 1-13 at page 9-20).

Generally, mere optimization of ranges will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimal or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *In re Peterson*, 315 F. 3d at 1330, 65 USPQ 2d at 1382; It has been held that it is within the skills in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 1980) MPEP 2114.04

Vandeveldt et al. does not expressly disclose the employment of tosylchloramide(s), in methods of the particular skin diseases herein.

Berger discloses the general teaching that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi. Furthermore, these skin diseases can be effectively treated with biocidal compositions that are used for disinfection (col. 7, line 61 to col. 8, line 8).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes.

One having ordinary skill in the art at the time the invention was made would

have been motivated to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes because: (1) Vandeveld et al. teach an antimicrobial pharmaceutical composition comprising tosylchloramide(s) and their salts for treating skin diseases; (2) Berger teaches that common skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi; and (3) Berger also give the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating skin diseases such as psoriasis and herpes with an antimicrobial composition comprising tosylchloramide(s) as disclosed by Vandeveld et al. because of the beneficial therapeutic effects of tosylchloramide(s) on killing and destroying harmful microorganisms that cause such skin diseases.

Response to Arguments

Applicant argues that Berger does not teach that skin diseases can be treated with any biocidal composition used for disinfection. Applicant then goes on to reference Berger that "the agent according to the invention and particularly the sodium chlorite solution can also be used for treating skin diseases..." (col. 8, lines 9-11).

This is not persuasive because the Berger reference was primarily used to show the general teaching that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi. In this manner, the Berger reference was not relied on for any teaching of therapeutically active agents.

Applicant submits Exhibit A, showing the PERMA-WASH disinfectant as having a warning to avoid contact with skin, eyes, or clothing.

This is not persuasive because Applicant has not established that this reference was published before the effective filing date of the instant application. Furthermore, it is not certain what chlorine dioxide has to do with tosylchloramide. Therefore, Exhibit A will not be considered at this time.

Applicant continues to argue that there is no indication in Vandeveldt that chloramine-T is suitable for the topical treatment of efflorescence skin diseases, much less herpes simplex virae. There is no motivation to combine the references and Examiner has improperly used hindsight reconstruction of Applicant's claims.

This is not persuasive because the primary reference, Vandeveldt, clearly teaches tosylchloramide(s) and its known derivatives, in particular, Chloramin T, for use in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases. Nonetheless, the mere mention that chloramine-T acts against viruses on inanimate objects provides sufficient motivation to administer a composition comprising chloramine-T as a medicament or a pharmaceutical composition for treating other skin diseases, such as herpes simplex virae, because one of ordinary skill in the art would have had a reasonable expectation of success in treating a viral disease. Applicant is reminded that the standard of obviousness is not absolute but a reasonable expectation of success.

In response to applicant's arguments against the references, one cannot show nonobviousness by attacking references individually where the rejections are based on

the combination of references. See *In re Keller*, 642 F. 2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claims 1, 3, 6-21, 34-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harwardt et al. (DE 41 37 544) in view of Berger (US Patent 4,574,084).

Harwardt et al. discloses that tosylchloramide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-4 and claims 1-7). Harwardt et al. discloses the pharmaceutical compositions of tosylchloramide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-5 at page 3-4).

Harwardt et al. does not expressly disclose the employment of tosylchloramide(s) in methods of the particular skin diseases herein.

Berger teach as discussed above.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes because: (1) Harwardt et al. teach an antimicrobial pharmaceutical composition comprising tosylchloramide(s) and their salts for treating skin diseases; (2) Berger teaches that common skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi; and (3) Berger also give the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating skin diseases such as psoriasis and herpes with an antimicrobial composition comprising tosylchloramide(s) as disclosed by Harwardt et al. because of the beneficial therapeutic effects of tosylchloramide(s) on killing and destroying harmful microorganisms that cause such skin diseases.

Response to Arguments

Applicant argues that Harwardt is not directed to treating skin diseases caused by herpes simplex virae, since the reference only discloses a combination of active ingredients for antiseptic and disinfection purposes. Applicant continues to argue that Harwardt teaches that single ingredients, for example chloramine-T alone, are not suited for antiseptic or disinfection purposes. Applicant also argues nonobviousness in combining Harwardt with the Berger reference since peroxide compounds as active ingredients.

This is not persuasive because Applicant has again attacked each reference individually for lacking the teaching that is provided for in the other reference. Although Harwardt does not teach treating skin diseases, the Berger reference teaches the nexus between skin diseases and disinfecting active ingredients. Specifically, the Berger reference teaches that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi, which can be effectively treated with biocidal compositions that are used for disinfection. Further, there is nothing in the Harwardt reference that teaches that chloramine-T alone is not suited for antiseptic or disinfection purposes. Furthermore, the argument regarding nonobviousness in combining the Harwardt and Berger references does not make sense since the Berger reference was not used for teaching any active ingredients and also since the claims use the open transitional phrase "comprising," so as to not preclude the inclusion of other active ingredients in the pharmaceutical composition.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S. Chong/
Primary Examiner, Art Unit 1617

YSC